DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 5, 2015

Accuthera, Inc.
% Mr. Robert Morton
CEO
Quality and Regulatory Services, Inc.
1244 Fairway Valley Court
LINCOLN CA 95648

Re: K143560
Trade/Device Name: CygneX I System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 3, 2015
Received: September 8, 2015

Dear Mr. Morton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143560

Device Name
CygneX I System

Indications for Use *(Describe)*
The CygneX I System is intended to provide treatment planning and surface-guided stereotactic radiosurgery and precision radiotherapy for lesions (e.g. arteriovenous malformations), tumors and conditions of the brain and base of skull (BOS).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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ACCUTHERA

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510(k) Summary

The following information is provided following the format of 21 CFR 807.92.

Submitter: Accuthera Inc.
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Date Summary was prepared: 10 December 2014

Name of the Device:

Trade/Proprietary Name: CygneX I System
Common or Usual Name: Medical Linear Accelerator
Classification Name: Medical charged-particle radiation therapy system
21 CFR 892.5050, Class II
Product Code: IYE

Predicate Device: Accuray CyberKnife System**,** K984563

Description of Device:

The CygneX I System consists of therapeutic CygneX I Treatment Delivery Subsystem and the dedicated CygPlan I Treatment Planning Subsystem. The CygneX I Treatment Delivery Subsystem consists mainly of a Therapeutic X-ray Generation Part, 6-Axis Manipulator Part, and X-ray Delivery Control Console Part. A linear accelerator with a variable collimator is incorporated in the X-ray head, the main portion of the Therapeutic X-ray Generation Part, which generates a very fine, highly- energized (6 MV) and controlled dose of X-ray beams. The variable secondary collimator is capable of delivering regular hexagonal fields, with the distances between the two opposite sides

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from 5mm to 30 mm, at 60 SAD. The CygPlan I Treatment Planning Subsystem provides the capability for forward and inverse planning from CT data. It provides a plan after physician approval, to the CygneX I Treatment Delivery Subsystem to deliver the treatment from the selected treatment nodes.

Statement of Intended Use:
The CygneX I System is a medical charged-particle radiation therapy system accelerating electrons intended to provide photon radiation for treatment.

Statement of Indications For Use:
The CygneX I System is intended to provide treatment planning and surface-guided stereotactic radiosurgery and precision radiotherapy for lesions (e.g. arteriovenous malformations), tumors and conditions of the brain and base of skull (BOS).

Summary of the Technological Characteristics:
The CygneX I System has same Intended Use, principles of operation, and major technological characteristics and a similar Indication For Use as the predicate device, the CyberKnife System For Stereotactic Radiosurgery/Radiotherapy, K984563, manufactured by Accuray, Inc.

A comparison table summarizing the similarities and differences between the CygneX I System and the predicate device is provided in Table ES-1.

Feature	Accuray CyberKnife System For Stereotactic Radiosurgery/Radiotherapy K984563	*Accuthera CygneX I System (CygneX I with CygPlan I)*	Consideration of the difference(s)
Intended Use	The CyberKnife System (K984563) is a medical charged-particle radiation therapy system accelerating electrons intended to provide photon radiation for treatment.	*The CygneX I System is a medical charged-particle radiation therapy system accelerating electrons intended to provide photon radiation for treatment.*	Same
Indication for use	To provide treatment planning and image-guided stereotactic radiosurgery and precision radiotherapy for lesions (e.g. arteriovenous malformations), tumors and conditions of the brain, base of skull (BOS), cervico-thoracic spine (CTS), head and neck.	*The System is intended to provide treatment planning and surface-guided stereotactic radiosurgery and precision radiotherapy for lesions (e.g. arteriovenous malformations), tumors and conditions of the brain and base of skull (BOS).*	No, but while it is less, it is included by the predicate.

Principles of Radiation delivery	The System is a type of stereotactic radiotherapy, a non-invasive treatment in which high doses of focused radiation beams are delivered from multiple locations outside of the body to destroy a tumor or lesion within the body. This minimizes radiation exposure to healthy tissue surrounding the tumor. The system uses a linear accelerator (Linac), producing the radiation while mounted on a robotic arm.	*The System is a type of stereotactic radiotherapy, a non-invasive treatment in which high doses of focused radiation beams are delivered from multiple locations outside of the body to treat a tumor or lesion within the body. This minimizes radiation exposure to healthy tissue surrounding the tumor. The system uses a linear accelerator (Linac), producing the radiation while mounted on a robotic arm.*	Same
Patient position monitoring	The predicate incorporates a fluoroscopic imaging device.	*CygneX I uses commercially available (510K cleared) positioning device for monitoring of the patient's body surface movement, such as AlignRT PLUS and a mobile C-Arm imaging or fluoroscopic system be used to confirm the target position, such as the Philips Veradius Neo System, K133819, or equivalent.*	No, but same safety can be achieved by confirmation of the patient position using a device which can image the position of the target inside the patient.
Technical characteristic			
Single dose and fractionated treatment	YES	*YES*	Same
X-band Accelerator	YES	*YES*	Same
X-ray energy	6MV(Standing wave Linac)	*6MV(Standing wave Linac)*	Same

Dose rate	300 cGy/min (maximum BUILD UP)	*300 cGy/min (maximum BUILD UP)*	Same
Isocenter floor height	127cm (nominal isocenter, system is not isocentric)	*130cm (nominal isocenter, system is not isocentric)*	No, but it is only 3 cm higher.
SAD	80cm	*60cm*	No, but it still treats the target to the prescribed dose.
Source Target positioning	Six-axis manipulator	*Six-axis manipulator*	Same
Patient Positioning device (Treatment Couch)	Stationary/Adjustable	*CygneX I System does not include a Treatment Couch. It uses commercially available Adjustable Treatment Couch which complies with conditions specified by Accuthera Inc.*	No, but same level of safety & effectiveness can be achieved by using a specified 510K cleared treatment couch.
Mechanical Isocenter accuracy	Less than 0.05cm radius	*Sphere less than 0.05cm radius*	Same
Dosimetry system reproducibility with position	±3% or 3MU whichever is greater at any fixed treatment node	*±2% or 1 MU whichever is greater at any fixed treatment node*	No, but has improved specification.
Beam collimation	Fixed secondary collimators delivering circular field sizes of 5, 7.5, 10, 12.5, 15, 20, 25, 30, 35, 40, 50 and 60 mm diameter at SAD	*Variable secondary collimator delivering regular hexagonal fields sizes, the distances between the two opposite sides are 5, 7.5, 10, 12.5, 15, 20, 25 and 30 mm at SAD*	Comparable field sizes up to 30 mm.
Target location reference	Patient's skull	*Patient's skull*	Same

Treatment Planning System	YES	*YES*	Same
Safety Interlocks	YES	*YES*	Same
Emergency Stop	YES	*YES*	Same

Table ES-1: Comparison of major feature of CygneX I System and the Predicate Device

Summary of Performance Testing:

There are some minor differences. However, comprehensive nonclinical testing in accordance with FDA Recognized Consensus Standards as shown in the TAB 8-2 and in the TAB-14, and testing in accordance with our internal performance specifications as shown in the TAB-15 demonstrates that the minor differences do not adversely impact performance of the device for its intended use nor do the differences raise new safety concerns. The nonclinical testing performed includes essential performance and basic safety testing, electromagnetic compatibility testing, functional performance characteristics testing and software verification and validation testing. All of these testing confirmed that the CygneX I System performs as intended.

Thus the CygneX I System is substantially equivalent to the Accuray CyberKnife System For Stereotactic Radiosurgery/Radiotherapy (K984563).